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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,510	03/24/2004	Tao Lu Lowe	059516-0058	3378

7590 04/16/2008  
MCDERMOTT, WILL & EMERY  
600 13th Street, N.W.  
Washington, DC 20005-3096

EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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04/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,510	<b>Applicant(s)</b> LOWE ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9 and 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The examiner acknowledges receipt of response to restriction requirement filed 1/24/08.

#### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-9 and 16-24 in the reply filed on 01/24/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant has further elected a hydrogel species so that claims 1-6, 8, 9 and 16-24 read on the elected species, claims 7 and 10-15 are withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-5 and 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The boundaries of elastin-like polypeptides and derivatives in claim 3 are not described.

The boundaries of derivatives in claims 4 and 5 are not described.

The meets and bounds of substance in claim 16 is not described.

Applicant may overcome the above rejection by deleting derivatives or specifically name what the derivatives are in the claims.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4-6, 8, 9, 16-21 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al. (WO 98/00170).

6. Hennink describes a hydrolysable hydrogels for controlled release of drugs such as protein drugs cytokine interleukin (abstract; page 1, lines 22-33; page 12, lines 14-31) with the hydrogel composition for the delivery of the protein drug meeting claims 16-19. The administration of the composition comprising the hydrolysable hydrogel polymer and the protein drugs to human (page 2, lines 4-19; page 3, line 30; page 5, lines 28 and 29; page 6, lines 7 and 8; and page 13, lines 9-19) meets the limitations of claims 20 and 21. The drugs in Henning are loaded into the hydrogel in an aqueous solution (page 4, lines 15-23; page 6, line 2) meeting claim 23. The hydrolysable polymer of Hennink has polyglycolic acid and or polylactic acid spacers between methacrylate type polymer and dextran (page 7, lines 24-36; pages 8; Examples 2, 3 and 4); the lactide or glycolide meets claim 4; the dextran meets claim 5 and the triblock polymer meets the generic polymer of claim 1 having the biodegradable segment, lactic acid and dextran and the smart segment, HEMA. Furthermore, the hydrogel composition is prepared in the form of microspheres (page 3, line 7; page 10, lines 26-34; page 12, line 7; page 13, line 21) meeting claim 8. Claims 2 and 9 recite the properties of the polymer and the polymer composition so that the polymer and polymer composition of Hennink meet those claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 3, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170) in view of Merchant (US 20020068087).

10. Hennink is discussed above as anticipating claims 1 and 2. Regarding claims 22 and 24, the artisan would have good reason to administer the composition having the appropriate concentration of the drug with the expectation that the delivery of the desired amounts of the drug would be released for effect the desired result. Hennink's polymer does not have the polymer of claim 3 as one of the polymers. However, hydrogel compositions containing poly N-isopropylacrylamide is a temperature sensitive polymer known to be used in the delivery of protein drugs such as interleukins (paragraphs [0014], [0087], [0088] and [0099]. Therefore, taking the general teaching of the references, one having ordinary skill in the art would have

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reasonable expectation of success using poly N-isopropylacrylamide in place of HEMA would produce a polymer that would be effective to deliver interleukin.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Examiner, Art Unit 1618